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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,010	12/14/2004	Ingemar Starke	056291-5188	4986

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MORGAN LEWIS & BOCKIUS LLP  
1111 PENNSYLVANIA AVENUE NW  
WASHINGTON, DC 20004

EXAMINER

COLEMAN, BRENDA LIBBY

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 04/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/518,010

Applicant(s)

STARKE ET AL.

Examiner

Brenda L. Coleman

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,4-9,13 and 14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4-9,13 and 14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>12/05 &amp; 1/06</u> . | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Claims 1, 4-9, 13 and 14 are pending in the application.

This action is in response to applicant's amendment filed December 30, 2005.

Claims 1, 4-9, 13 and 14 have been amended and claims 2, 3, 10-12 and 15-21 have been canceled.

### *Response to Amendment*

Applicant's arguments filed December 30, 2005 have been fully considered with the following effect:

1. The applicant's amendments and arguments are sufficient to overcome the 35 USC § 112, first paragraph rejection of claims 1-21, labeled paragraph 2 of the last office action, which is hereby **withdrawn**.
2. With regards to the 35 U.S.C. § 112, first paragraph rejection of claims 10-21, labeled paragraph 3, the applicants' remarks concerning claim 13 were such that "claim 13 differs from the Examiner's assertions in that it recites the direct action of the presently claimed compounds in inhibiting IBAT in a warm-blooded animal, rather than the treatment of one or more specific disease or medical conditions". The applicant's also stated that the specific disclosure at page 16, lines 22-27 or the specification with respect to test assays to determine the IBAT inhibitory activity of the claimed compounds. However, page 16, lines 22-27 do not contain this information. Furthermore, as stated in the last office action it is difficult to treat many of the disorders claimed herein.

Where the utility is unusual or difficult to treat or speculative, the examiner has authority to require evidence that tests relied upon are reasonably predictive of in vivo efficacy by those skilled in the art. See *In re Ruskin*, 148 USPQ 221; *Ex parte Jovanovics*, 211 USPQ 907; MPEP 2164.05(a).

Patent Protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. Tossing out the mere germ of an idea does not constitute enabling disclosure. *Genentech Inc. v. Novo Nordisk* 42 USPQ2d 1001.

As stated in the MPEP, 2164.08 "[t]he Federal Circuit has repeatedly held that the specification must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557, 1561 27 USPQZd 1510, 1513 (Fed. Cir. 1993). Nevertheless, not everything necessary to practice the invention need be disclosed. In fact, what is well known is best omitted. *In re Buchner*, 929 F.2d 660, 661, 18 USPQZd 1331, 1332 (Fed. Cir. 1991). All that is necessary is that one skilled in the art be able to practice the claimed invention, given the level of knowledge and skill in the art. Further the scope of enablement must only bear a reasonable correlation to the scope of the claims. See, e.g., *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). As concerns the breadth of a claim relevant to enablement, the only relevant concern should be whether the scope of enablement provided to one skilled in the art by the disclosure is commensurate with the scope of protection sought by the claims. *In re Moore*, 439 F.2d 1232, 1236, 169 USPQ 236, 239 (CCPA 1971). See also *Plant Genetic Sys., N.V. v. DeKalb Genetics*

Corp., 315 F.3d 1335, 1339, 65 USPQ2d 1452, 1455 (Fed. Cir. 2003) (alleged pioneer status of invention irrelevant to enablement determination."

Claims 13 and 14 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for reasons of record and stated above.

3. The applicant's amendments and arguments are sufficient to overcome the 35 USC § 112, first paragraph rejection of claims 15-21, labeled paragraph 4 of the last office action, which is hereby **withdrawn**.

4. The applicants' amendments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejections labeled paragraph 5a), b), c), d) and f) of the last office action, which are hereby **withdrawn**. However, with regards to the 35 U.S.C. § 112, second paragraph rejection labeled 5e) of the last office action, the applicant's amendments and remarks have been fully considered but they are not persuasive.

e) The applicant's stated that the Examiner has not made out an appropriate rejection under section 112, second paragraph, and that the rejection is at best a duplicate of the section 112, first paragraph rejection set out in paragraph 3 of the Action, beginning with the first full paragraph on page 4 of the Action, which was addressed and overcome at pages 21-23 above. First, the applicants have not overcome the 112, first paragraph rejection with respect to claims 13 and 14. In addition to being rejected under 112, first paragraph, claim 13 is also rejected

under 112, second paragraph in that a method of inhibiting IBAT is indefinite in that it is not known which diseases are capable of being responsive to the activity of inhibiting IBAT. The scope of diseases and/or disorders associated with the activity of IBAT could alter over time. The applicants' are not entitled to preempt the efforts of others. Thus the applicants have not set forth the metes and bounds of the claim.

Claim 13 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

5. The applicants' amendments are sufficient to overcome the 35 U.S.C. § 101, rejection labeled paragraph 6 in the last office action, which is hereby **withdrawn**.
6. The applicants' amendments and arguments are sufficient to overcome the obviousness-type double patenting rejection of claims 1-14, labeled paragraph 7 in the last office action, which is hereby **withdrawn**.
7. The applicants' amendments are sufficient to overcome the provisional obviousness-type double patenting rejection of claim 20, labeled paragraph 8 in the last office action, which is hereby **withdrawn**.
8. The applicants' amendments are sufficient to overcome the provisional obviousness-type double patenting rejection of claim 20, labeled paragraph 9 in the last office action, which is hereby **withdrawn**.

9. With regards to the provisional obviousness-type double patenting rejection of claims 12-21, labeled paragraph 10 as being unpatentable over claims 1-20 of copending Application No. 10/502,355 of the last office action, the applicants requested that this rejection be held in abeyance at this time.

Claims 13 and 14 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 6, 8, 10, 13, 14 and 18-20 of copending Application No. 10/502,355, for reasons of record and stated above.

10. The applicants' amendments and arguments are sufficient to overcome the provisional obviousness-type double patenting rejection of claims 10-21, labeled paragraph 11 in the last office action, which is hereby **withdrawn**.

11. The applicants' amendments are sufficient to overcome the provisional obviousness-type double patenting rejection of claim 20, labeled paragraph 12 in the last office action, which is hereby **withdrawn**.

12. With regards to the provisional obviousness-type double patenting rejection of claims 1-21, labeled paragraph 13 as being unpatentable over claims 1-25 of copending Application No. 10/488,540 of the last office action, the applicants requested that this rejection be held in abeyance at this time.

Claims 1, 4-9, 13 and 14 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12,

17 and 18 of copending Application No. 10/488,540, for reasons of record and stated above.

13. With regards to the provisional obviousness-type double patenting rejection of claims 1-21, labeled paragraph 14 as being unpatentable over claims 1-16, 20-69 and 73-76 of copending Application No. 10/451,262 of the last office action, the applicants requested that this rejection be held in abeyance at this time.

Claims 1, 4-9, 13 and 14 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16, 20, 21 and 29 of copending Application No. 10/451,262, for reasons of record and stated above.

14. The applicants' amendments are sufficient to overcome the objection of claims 10-21 in the last office action, which is hereby **withdrawn**.

In view of the amendment dated December 30, 2005, the following new grounds of rejection apply:

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

15. Claims 1, 4, 6, 7, 9, 13 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reason(s) apply:



- a. Claims 1, 4, 6, 7, 9, 13 and 14 are vague and indefinite in that it is not known what is meant by the moiety methylS(O)<sub>a</sub> in the definition of R<sup>4</sup>. It is believed that the applicants intended methylS(O)<sub>a</sub>.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda L. Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Brenda L. Coleman  
Primary Examiner Art Unit 1624  
April 3, 2006